

## PROPOSED RULES

[4110-03]

DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 207, 607, 807]

[Docket No. 77N-0255]

## MEDICAL DEVICES

## Device Listing Procedures

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

**SUMMARY:** This proposal prescribes procedures for listing medical devices pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and sets forth who must list devices, the times for listing, and how and when devices must be listed.

**DATES:** Comments by November 29, 1977. The Commissioner proposes that the final regulations based on this proposal shall be effective on October 31, 1977.

**ADDRESS:** Written comments (four copies) to the Hearing Clerk (HFC-20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

## FOR FURTHER INFORMATION CONTACT:

Thomas V. Kelley, Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910 (301-427-7190).

**SUPPLEMENTARY INFORMATION:** Final regulations for Part 807 (21 CFR Part 807) governing establishment registration were published in the *Federal Register* of August 23, 1977 (42 FR 42520). This proposal amends Part 807 to prescribe the information required to satisfy the device listing requirements of section 510 of the act.

In the *Federal Register* of December 28, 1976 (41 FR 56397), the Food and Drug Administration (FDA) gave notice of the agency's procedures for implementing the device listing requirements. The notice informed owners and operators of medical device establishments that FDA would not require device listing information by December 31, 1976, but would rather, as discussed below, implement the device listing requirements in 1977 by mailing the necessary procedures, forms, and other related information to the official correspondent for each registered establishment.

Section 510(j) of the act requires every person who registers with FDA to file a list of all devices being manufactured, prepared, propagated, compounded or processed by him for commercial distribution. This list is to be prepared in such form and manner as the Commissioner may prescribe.

Section 510(j) of the act also requires the submission of the following additional information with the device list-

ing: the listing for a device for which a performance standard has been established under section 514 of the act (21 U.S.C. 360d) or which is subject to section 515 of the act (21 U.S.C. 360e) must be accompanied by a reference to the authority for the marketing of the device and a copy of all labeling for such device; the listing for a restricted device must be accompanied by a copy of all labeling for the device, a representative sampling of advertisements for the device, and, upon request made by the Commissioner for good cause, a copy of all advertisements for the device; the listing of a device that is not a restricted device must be accompanied by the label and package insert for the device and a representative sampling of any other labeling for the device; if the registrant has determined that a particular device is not subject to sections 514 or 515 of the act or is not a restricted device, the Commissioner may request the submission of a brief statement of the basis upon which the registrant made such determination; the listing for all devices must be accompanied by a statement of the basis for believing that the product listed is a device and not a drug.

Section 510(j) of the act also provides for the updating of device listing information. Updating information must be submitted once during the month of June each year and once during the month of December each year. At that time, registrants must submit to FDA: a list of all devices introduced by the registrant for commercial distribution that have not been included in any list previously filed by him with FDA, a list of all devices for which the registrant has discontinued commercial distribution, a list of all devices for which the registrant has previously filed a notice of discontinuance with FDA and for which the registrant has resumed commercial distribution, and any material change in any information previously submitted pursuant to section 510(j) of the act. A new listing of a device or a notice of resumption of commercial distribution of a device must be accompanied by the appropriate labels, labeling, and advertisements for the device, as noted above.

## DEFINITIONS

The Commissioner is proposing to add to § 807.3 a new paragraph (i) that defines "restricted device" to mean a device for which the Commissioner, by regulation under § 801.109 (21 CFR 801.109) or otherwise under section 520(e) of the act (21 U.S.C. 360j(e)), has restricted to sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe in the regulation. For devices in commercial distribution before enactment of the Medical Device Amendments of 1976, the definition includes all devices designated as prescription devices by § 801.109. A postenactment "restricted device" is a device so designated under section 520(e) of the act. For example, in the *Federal Register* of February 15,

1977 (42 FR 9386), FDA issued final regulations that placed conditions for sale and other restrictions on the distribution of hearing aids, thus making hearing aids restricted devices.

The Commissioner is also proposing to add to § 807.3 (21 CFR 807.3) a new paragraph (j) that defines "classification name" to mean the term used by the classification panels in the classification process under section 513 of the act (21 U.S.C. 360c) to describe a device of class of devices. The use of this term will facilitate the collection, organization, and retrieval of device listing information in that a list of "classification names" will be provided by FDA to persons required to submit such listing information.

The Commissioner is also proposing, for clarity, definitions for "representative sampling of advertisements" and "representative sampling of any other labeling" in proposed § 807.3 (k) and (l), respectively.

## WHO MUST LIST DEVICES

Any owner or operator of a device establishment required to register under Part 807 is also required to list all devices. The registration and listing requirements shall pertain to any person who:

1. Initiates or develops specifications for a device that is to be manufactured for him for subsequent commercial distribution by him.

2. Manufacturers for commercial distribution a device either for himself or for another person.

3. Repackages or relabels a device.

4. Initially distributes a device imported into the United States.

5. Manufacturers components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified persons to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks. Any owner or operator who is exempted from the registration requirements is also exempted from the listing requirements.

Proposed § 807.20 (21 CFR 807.20) has been amended to provide that listing information may be submitted by the parent, subsidiary and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. Listing information must be submitted whether or not the output of the establishment or any particular device so listed enters interstate commerce.

## TIMES FOR LISTING

The agency intends to implement device listing immediately, before the effective date of the final regulation based on this proposal. Section 510 of the act is self-executing, i.e., its effectiveness does not depend on promulgation of agency

regulations. Owners and operators of establishments that are required to register must comply with the device listing requirements by December 31, 1977, regardless of whether FDA has published final device listing regulations that prescribe the form and manner for preparation of the list, and thus aid owners and operators of device establishments in complying with the statute.

Device listing forms will be mailed to all official correspondents, as defined in the establishment registration regulations (21 CFR 807.3(e)) and will also be available from FDA upon request in accordance with the proposed regulation. Owners or operators required to submit device listing must submit the initial listing of all devices they have in commercial distribution within 90 days of receiving the device listing package from FDA, but no later than December 31, 1977. An extension of this deadline will be considered for those owners or operators who specify a need for an extension in writing to the Bureau of Medical Devices (HFK-124), Registration and Listing Section, Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. Such requests must include the reason(s) for requesting an extension, the approximate number of forms to be submitted, and a date when the owner or operator will complete the listing requirement.

Owners or operators who have not previously entered into an operation requiring device listing must submit their device listing information within 30 days after entering into such an operation. Owners or operators may update their device listing information at any time, but are required to do so each June and December, in accordance with proposed § 807.30 (21 CFR 807.30).

#### HOW AND WHERE TO SUBMIT LISTING

Form FD-2892 (Medical Device Listing) is the approved form for submitting device listing information. A supply of these forms will be mailed to all establishments registered with FDA. These forms may be obtained upon request from the Registration and Listing Section at the address set forth above or from FDA district offices.

Proposed § 807.22(b) (21 CFR 807.22(b)) provides that a separate Form FD-2892 must be submitted for each device or device class listed with FDA. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device, provided the variation does not change the function or intended use of the device.

Proposed section 807.22(c) provides that the initial distributor of an imported device is not required to submit a Form FD-2892 for each such device. But he shall submit, for each device for which he is the initial distributor, the name and address of the foreign manufacturer. He must also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which he is the ini-

tial distributor. The foreign manufacturer is required by proposed § 807.40 to list his devices. The requirements of §§ 807.22(c) and 807.40 will provide FDA with a cross-check system to assure that foreign manufacturers comply with the device listing requirements.

#### INFORMATION REQUIRED IN A DEVICE LISTING

Proposed § 807.25(f) (21 CFR 807.25(f)) describes the information required to be included on Form FD-2892.

Proposed § 807.25(f) (1) requires that devices be listed on Form FD-2892 by classification name, proprietary name, if any, and common or usual name. The agency will provide a list of classification names for devices when it sends official correspondents copies of Form FD-2892. This list, compiled by FDA advisory committees that are serving as device classification panels, will facilitate the collection, organization, and retrieval of the required device listing information, thereby simplifying the task of processing the large amount of listing information expected. Owners and operators will be able to list multiple variations of a device under one classification name, thus reducing the reporting burden for the owner or operator and the processing requirements for FDA. Use of classification names will also provide the basis for identifying manufacturers of class II and class III devices who are subject to mandatory biennial inspection under section 510(h) of the act and will identify devices that have not been classified.

Section 510(j) (1) (A) of the act requires that a device list include a reference to the authority for the marketing of a device for which a performance standard has been established under section 514 of the act or which is subject to section 515 of the act. Proposed § 807.25(f) (2) and (3) implement this provision.

Proposed § 807.25(f) (2) requires that when a device is subject to a performance standard under section 514 of the act or section 358 of the Public Health Service Act as amended by the Radiation Control for Health and Safety Act, the registrant must enter the Code of Federal Regulations citation for the applicable standard.

Proposed § 807.25(f) (3) requires that when a device is the subject of an approved premarket approval application pursuant to section 515 of the act, or an approved new drug application pursuant to section 505 of the act, or an approved antibiotic form 5 or 6 pursuant to section 507 of the act, the registrant shall enter its assigned FDA number.

Proposed § 807.25(f) (4) requires that the registrant enter the name and registration number of every establishment at which the listed device is manufactured, repackaged, or relabeled. The registration number is the seven digit number in block 12 of Form FD-2891 (Initial Registration of Device Establishment) assigned at the time of registration.

Proposed § 807.25(f) (5) requires that when the registrant is unable to find an appropriate classification name for his device on the list provided by FDA in

the device listing package, he must submit labeling adequate to describe the intended use of the device. FDA then will assign an appropriate classification name.

#### UPDATING DEVICE LISTING

Proposed § 807.30(a) requires that Form FD-2892 be used for updating device listing information.

The FDA control of each Form FD-2892 will be based on the use of the original document number that is printed in block 1 on each Form FD-2892. This original document number shall appear in block 2 on any form subsequently used to update the listing information for the device and on any correspondence relating to the device.

Proposed § 807.30(b) requires the registrant to update his device listing information each June and December if any change has occurred in any information included on the Form FD-2892 since his last report. The registrant is encouraged, however, to report a change at the time it occurs.

The following changes require the submission of Form FD-2892 to update device listing information:

1. The introduction by the registrant into commercial distribution of a device if he does not currently have listed with FDA a device of the same classification name. A complete form must be submitted for such a device, even if the device had been the subject of a premarket notification submission.

2. The discontinuance of commercial distribution of a device if the registrant is discontinuing commercial distribution of all devices of the same classification name. The device shall be identified by the classification name, proprietary name, if any, the common or usual name, the original document number, and the date of discontinuance. It is requested, but not required, that the reason for discontinuance of distribution be included with this information.

3. The resumption of commercial distribution of a device that had been previously listed with FDA is discontinued. The device shall be identified by the classification name, proprietary name, and common or usual name of the device, the original document number, and the date of resumption.

4. Any material change in any information previously submitted.

Proposed § 807.30(c) provides that updating is not required in June and December if no change has occurred since the previous submission.

#### ADDITIONAL INFORMATION

Section 510(j) of the act requires that the listing information filed with FDA also include labels, labeling and, in some cases, advertisements. A liberal interpretation of the act would lead to the submission of, and require the subsequent storage of, information that FDA may not have immediate need for and, unless constantly updated by the owner or operator, would be out of date when needed. To alleviate this problem, the Commissioner is proposing in § 807.31 (21 CFR 807.31) to require that the owner

or operator maintain a historical file of labels, labeling, and, for restricted devices, advertisements, and make all or part of that file available to FDA upon request. The Commissioner does not believe this imposes a major burden on industry because maintaining such information is consistent with good manufacturing practice.

Labels, labeling, and advertisements will be requested by letter. In certain cases in the instructions accompanying Form FD-2892, FDA requests that labels or labeling be submitted along with the device listing form.

Section 510(j)(1)(D) of the act provides that the Commissioner may request, for a particular device, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act. Section 807.31(b)(3) implements this provision.

Proposed § 807.31(b)(4) also requires that the owner or operator must provide, when requested by FDA, a statement of the basis for believing that the device listed is a device and not a drug. Section 510(j) of the act requires that such a statement be included in the listing information. The Commissioner believes that, in most cases, it will be obvious that the product is a device and not a drug and is therefore requiring that this statement only be submitted when requested.

Finally, proposed § 807.31(b)(5) provides that owners or operators who manufacture devices for distribution under labels other than their own must, upon request, furnish FDA with a list of these private label distributors for whom they manufacture devices. In the case of private label distributors, identical devices may be marketed under many different distributor labels without identifying the manufacturer. Private label distributors are exempted from registration and listing. The agency does not want the same device listed numerous times (by the manufacturer and by each distributor). But in certain situations, such as a device recall, it becomes necessary to know all private label distributors of a device. Proposed § 807.31(b)(5) would assure that FDA can obtain this information in these situations.

#### PUBLIC DISCLOSURE OF DEVICE LISTINGS

Under proposed § 807.37(b) (21 CFR 807.37(b)), the information submitted pursuant to these device listing procedures will generally be available for public disclosure. This includes all Forms FD-2892 submitted. It also includes all labels, labeling, and advertisements that have been submitted and all other data and information submitted that has become a matter of public knowledge.

#### PROCEDURES FOR FOREIGN ESTABLISHMENTS

Proposed § 807.40(b) requires that every foreign device establishment that exports devices into the United States shall comply with the device listing requirements whether or not the establishment is also registered, unless it falls within the exemptions from registration in § 807.65.

Proposed § 807.40(c) provides that a device may not be imported from a foreign device establishment into the United States, except a device imported or offered for import that has in effect an approved exemption for investigational use pursuant to FDA regulations under section 520(g) of the act unless it is first the subject of a device listing. The device listing information shall be in the English language. (FDA regulations under section 520(g) of the act were proposed in the FEDERAL REGISTER of August 20, 1976 (41 FR 35282).)

Proposed § 807.40(d) provides that foreign device establishments shall submit, as part of the device listing, the name and address of the establishment and the name of the individual responsible for submitting device listing information. Any changes in this information shall be reported to FDA at the intervals specified for updating device listing information.

#### NATIONAL HEALTH RELATED ITEMS CODE

The agency has supported the National Health Related Items Code (NHRIC) as a system for the identification and numbering of marketed device packages. The use of this number provides compatibility with other numbering systems such as the National Drug Code (NDC) and Universal Product Code (UPC). The support of this system in addition to device listing would require some duplication in reporting on the part of manufacturers and distributors and processing on the part of FDA.

The agency now plans to limit the support of the NHRIC system and no longer maintain the NHRIC data base. Those manufacturers and distributors who desire to use the NHRIC number for unique product identification may apply to FDA for a labeler code. This labeler code is the first segment in the two-segment NHRIC system. Participating manufacturers and distributors will then complete the code by identifying their devices with a sequential number. The manufacturer or distributor will then assume responsibility for maintaining this number.

Those manufacturers or distributors currently participating in the NHRIC system may continue to use the numbers assigned, but no longer should submit update information to FDA.

The agency proposes no requirement for placing the NHRIC number on device labels, but those manufacturers or distributors choosing to do so should display it prominently in the top third of the principal display panel.

When placed on device labels, the NHRIC number should be preceded by the letter H to distinguish it from NDC or UPC numbers. Manufacturers and distributors of in vitro diagnostic products previously assigned NDC numbers may retain those numbers, but are requested to change the prefix from N to H as label revisions occur.

Comments are requested from those manufacturers or distributors interested in such numbering systems.

#### ENVIRONMENTAL IMPACT

The Commissioner has determined that the proposed regulation is not covered by § 25.1(b) (21 CFR 25.1(b)) and, as a result, consideration by FDA of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 301(p), and (q)(2), 501, 502, 508, 510, 518, 701(a), 52 Stat. 1042-1043 as amended, 1049-1050 as amended, 1055, 90 Stat. 576-580 (21 U.S.C. 331(p) and (q)(2), 351, 352, 358, 360, 3601, 371(a))) and under authority delegated to the Commissioner 21 CFR 5.1 is proposed that Parts 207, 607, and 807 be amended as follows:

#### PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. In Part 207, by amending § 207.65(d) by adding a sentence at the end of the paragraph, as follows:

§ 207.65 Exemptions for domestic establishments.

(i) . . . This paragraph does not exempt such persons from registration and listing for medical devices required under Part 807 of this chapter.

#### PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

2. In Part 607, by amending § 607.65 (e) by adding a sentence at the end of the paragraph, as follows:

§ 607.65 Exemptions for blood product establishments.

(e) . . . This paragraph does not exempt such persons from registration and listing for medical devices required under Part 807 of this chapter.

#### PART 807—ESTABLISHMENT REGISTRATION FOR MANUFACTURERS OF DEVICES

3. Part 807 is amended as follows:

a. In § 807.3, by adding new paragraphs (i), (j), (k), and (l) to read as follows:

§ 807.3 Definitions.

(i) "Restricted device" means a device for which the Commissioner, by regulation under § 801.109 of this chapter or otherwise under section 520(e) of the act, has restricted sale, distribution or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe.

(j) "Classification name" means the term used by the Food and Drug Administration and its classification panels to describe a device or class of devices for purposes of classifying devices under section 513 of the act.

(k) "Representative sampling of advertisements" means typical advertising material that gives a balanced picture of the promotional claims being used for the device.

(l) "Representative sampling of any other labeling" means typical labeling material (excluding labels and package inserts) that gives a balanced picture of the promotional claims being used for the device.

b. In § 807.20, by revising the section heading, introductory text of paragraph (a), and paragraph (b), to read as follows:

**§ 807.20 Who must register and submit a device list.**

(a) Any owner or operator of an establishment not exempt under section 510(g) of the act or Subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly or processing of a device intended for human use is required to register and to submit a list of every device in commercial distribution (except that listing information may be submitted by the parent, subsidiary, or affiliate company for all the establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). The term device includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. Such owner or operator is required to register his name, places of business, and all such establishments and to list such devices whether or not the output of such establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(b) No registration or listing fee is required. Registration or listing does not constitute an admission or agreement or determination that a product is a "device" within the meaning of section 201(h) of the act.

c. By revising § 807.21, to read as follows:

**§ 807.21 Times for establishment registration and device listing.**

The owner or operator of an establishment entering into, or currently engaged in, an operation defined in § 807.3(c) and not currently registered shall register the establishment by October 22, 1977. The owner or operator of an establishment who has not previously entered into an operation defined in § 807.3(c) shall register within 30 days after entering into such an operation and submit device listing information at that time. Owners or operators of all establishments shall update their registration information annually between November 15 and December 31 and shall update their device listing information every June and December.

d. By revising § 807.22, to read as follows:

**§ 807.22 How and where to register establishments and list devices.**

(a) The first registration of a device establishment shall be on Form FD-2891 (Initial Registration of Device Establishment). Forms are obtainable on request from the Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, or from the Food and Drug Administration district offices. Subsequent annual registration shall be accomplished on Form FD-2891(a) (Registration of Device Establishment), which will be furnished by the Food and Drug Administration before November 15 of each year to establishments whose registration for that year was validated pursuant to § 807.35(a). The completed form shall be mailed to the above-designated address before December 31 of that year.

(b) The initial listing of devices and subsequent June and December updates shall be on Form FD-2892 (Medical Device Listing). Forms are obtainable upon request as described in paragraph (a) of this section. A separate Form FD-2892 shall be submitted for each device or device class listed with the Food and Drug Administration. Devices having variations in physical characteristics such as size, package, shape, color, or composition should be considered to be one device, provided the variation does not change the function or intended use of the device. In lieu of Form FD-2892, tapes for computer input may be submitted if equivalent in all elements of information as specified in Form FD-2892. All formats proposed for use in lieu of Form FD-2892 require initial review and approval by the Food and Drug Administration.

(c) The initial distributor within the United States of an imported device is not required to submit a Form FD-2892 for each such device. However, he shall submit, for each device for which he is the initial distributor, the name and address of the foreign manufacturer. The initial distributor shall also be prepared to submit, when requested by the Food and Drug Administration, the proprietary name, if any, and the common or usual name of each device for which he is the initial distributor. The initial distributor shall update the information required by this paragraph at the intervals specified in § 807.30.

e. In § 807.25, by revising the section heading and by adding new paragraph (f), to read as follows:

**§ 807.25 Information required or requested for establishment registration and device listing.**

(f) Form FD-2892 is the approved form for providing the device listing information required by the act. This required information includes the following:

(1) The identification by classification name, proprietary name, and common or

usual name of each device that is being manufactured, prepared, propagated, compounded or processed for commercial distribution that has not been included in any list of devices previously submitted on Form FD-2892.

(2) The Code of Federal Regulations citation for any applicable standard for the device under section 514 of the act or section 358 of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act.

(3) The assigned Food and Drug Administration number of the approved application for each device listed that is subject to section 505, 507, or 515 of the act.

(4) The name and registration number of every device establishment at which the device is manufactured, repackaged, or relabeled.

(5) Labeling adequate to describe the intended use of a device when the owner or operator is unable to find an appropriate classification name for his device on the list provided by the Food and Drug Administration in the device listing package.

f. By adding new § 807.30, to read as follows:

**§ 807.30 Updating device listing information.**

(a) Form FD-2892 shall be used to update device listing information. The original document number preprinted on each Form FD-2892 shall appear in block 2 on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

(b) The owner or operator shall update his device listing information during each June and December or, at his discretion, at the time the change occurs. The following information shall be submitted:

(1) All the information required by § 807.25(f) for each device that the owner or operator has introduced into commercial distribution, if the owner or operator does not currently have listed a device with the same classification name.

(2) The identification by classification name, proprietary name, and common or usual name of each device previously listed pursuant to § 807.25(f) for which commercial distribution has been discontinued, the original document number, and the date of discontinuance. No report is required unless the manufacturer has discontinued commercial distribution of all devices with the same classification name. It is requested but not required that the reason(s) for discontinuance of distribution be included with this information.

(3) The identification by classification name, proprietary name, and common or usual name of each device for which a notice of discontinuance was submitted pursuant to paragraph (b)(2) of this section and for which commercial distribution has been resumed; the date of resumption; the original document number which appears in block 1 of Form

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FD-2892; and any other information required by § 807.25(f) not previously submitted.

(4) Any material change in any information previously submitted.

(c) Updating is not required if no change has occurred since the previously submitted list.

g. By adding new § 807.31, to read as follows:

**§ 807.31 Additional listing information.**

(a) Each owner or operator shall maintain a historical file containing all labels and labeling for every device and advertisements for each restricted device.

(b) Each owner or operator shall be prepared to submit to the Food and Drug Administration the information listed below. This information shall be submitted to the Food and Drug Administration only upon specific request:

(1) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and, for good cause, a copy of all advertisements for a particular device.

(2) For a device that is not a restricted device, the label and package insert for the device and a representative sampling of any other labeling for the device.

(3) For a particular device, upon request by the Commissioner, a statement of the basis upon which the registrant has determined that the device is not subject to section 514 or 515 of the act.

(4) For a particular device, a statement of the basis for believing that the product is a device rather than a drug.

(5) For a device that the owner or operator has manufactured for distribution under a label other than his own, the names of all distributors for whom it has been manufactured.

h. In § 807.35, by revising paragraph (c) to read as follows:

**§ 807.35 Notification of registrant.**

(c) Although establishment registration and device listing are required to engage in the device activities described in § 807.20, validation of registration and the assignment of a device listing number in itself does not establish that the

holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Food and Drug Administration as to the status of any device.

1. By revising § 807.37, to read as follows:

**§ 807.37 Inspection of establishment registrations and product listings.**

(a) A copy of the Form FD-2891 and FD-2891(a) filed by the registrant will be available for inspection pursuant to section 510(f) of the act, at the Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of registration number or location of a registered establishment will be provided.

(b) (1) The following information filed pursuant to the device listing requirements will be available for public disclosure:

(i) Each Form FD-2892 submitted.

(ii) All labels submitted.

(iii) All labeling submitted.

(iv) All advertising submitted.

(v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b) (1) of this section should be directed to the Bureau of Medical Devices (HFK-124), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910.

(3) Requests for device listing information not identified in paragraph (b) (1) of this section shall be submitted and handled in accordance with Part 20 of this chapter.

j. By revising § 807.40, to read as follows:

**§ 807.40 Establishment registration and product listing for foreign manufacturers of devices.**

(a) Foreign device establishments that export devices into the United

States are requested to register in accordance with the procedures of Subpart B of this part, unless exempt under Subpart D of this part.

(b) Foreign device establishments that export devices into the United States, whether or not the establishment is registered, shall comply with the device listing requirements unless exempt from registration as stated in § 807.65.

(c) A device may not be imported from a foreign device establishment into the United States, except a device imported or offered for import that has in effect an approved exemption for investigational use pursuant to section 520(g) of the act, unless it is first the subject of a device listing. The device listing information shall be in the English language.

(d) Foreign device establishments shall submit, as part of the device listing, the name and address of the establishment and the name of the individual responsible for submitting device listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating device listing information in § 807.30(a).

Interested persons may, on or before November 21, 1977 submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107. A copy of the inflation impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: September 22, 1977.

WILLIAM F. RANDOLPH,  
Acting Associate  
Commissioner for Compliance.

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